MISSOURI BOARD OF PHARMACY

Pharmacy Self-Assessment Form

AUGUST 2023

MISSOURI DIVISION OF
PROFESSIONAL REGISTRATION
3605 MISSOURI BOULEVARD
JEFFERSON CITY, MISSOURI 65109

REVISED

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Missouri Pharmacist Self-Assessment

The Pharmacy Self-Assessment tool is provided by the Board of Pharmacy to assist pharmacies in assessing their compliance with Missouri pharmacy requirements. Compliance violations are preventable! Regular assessment can help detect, prevent and resolve compliance issues prior to an inspection.

Who can benefit from this assessment?

- Pharmacist-in-Charge
- Pharmacy Permitholders
- Pharmacy Owners
- Pharmacy Supervisors
- Risk, Compliance or Quality Assurance Staff

How to use this assessment

To maximize value, the Self-Assessment should be completed when you have sufficient time to adequately review the pharmacy's compliance activities. Do not assume you are in compliance! Physically review the pharmacy's records and policies and procedures to determine compliance with each assessment standard listed. Skipping this process could lead to missed areas of non-compliance. Assessment standards marked "no" likely indicate a compliance violation/concern and should be immediately corrected. Note: The Self-Assessment includes the most frequently identified compliance violations and does not constitute an exhaustive list of all compliance criteria. Your inspector will review additional compliance requirements during an inspection.

When to use this assessment

Compliance monitoring and education should be an on-going activity. Licensees are encouraged to use this tool as often as necessary. At a minimum, the Board recommends an annual assessment. The Board also recommends an assessment if the pharmacy experiences a change in:

- Pharmacist-in-charge
- Pharmacy Ownership
- Risk, Compliance or Quality Assurance Managers
- Significant staff changes

Continuing education credit

The Board has approved two (2) hours of pharmacy continuing education (CE) credit for Missouri licensed pharmacists serving as a pharmacy manager, owner, supervisor, corporate officer or the pharmacist-in-charge. CE is available for each calendar year licensees completes the Self-Assessment. To be eligible for CE, the attached Certification Form must be returned to the Board before December 31st of the applicable calendar year. Self-Assessments completed after the biennial continuing education deadline will not be eligible for credit for the preceding renewal period.

After the assessment

Review your results carefully. Self-Assessment standards marked "no" may signal areas of non-compliance. Review the law and take corrective action immediately. Discuss results with pharmacy staff and identify ways to remain compliant. Remember, compliance is a team effort!

Respond to all applicable Assessment Standards. Mark "yes" if the pharmacy is in compliance. Standards marked "no" may indicate non-compliance.

LICENSING

STANDARD	RESPONSE	CITE
1. The pharmacy's permit is current and posted.	YES NO N/A	20 CSR 2220-2.020(5)
2. The name of the current pharmacist-in-charge is listed on the pharmacy's permit. *Interim supervising pharmacists will not be on the permit.*	YES NO N/A	20 CSR 2220-2.010(1)(M)
3. The classifications listed on the pharmacy's permit are correct and accurate. • A classification change form must be filed with the Board if a function has been added/deleted.	YES NO N/A	20 CSR 2220-2.020(10)
4. The pharmacy has a Class-C: Long-Term Care permit if the pharmacy is dispensing to patients in a long-term care facility (e.g., a nursing home, retirement facility, mental care facility or any other facility that provides extended care to resident patients).	YES NO N/A	20 CSR 2220-2.020(9)(C)
5. The pharmacy has a Class-D: Non-Sterile Compounding permit if the pharmacy is engaged in non-sterile compounding in batch quantities using bulk ingredients.	YES NO N/A	20 CSR 2220-2.020(9)(D)
6. The pharmacy has a Class-H: Sterile Compounding permit if the pharmacy is engaged in sterile compounding. A Class-H permit is required to compound bladder irrigation products.	YES NO N/A	20 CSR 2220-2.020(9)(H)
7. The pharmacy has a Class-J: Shared Services permit if pharmacy services are provided to, or received from, another pharmacy.	YES NO N/A	20 CSR 2220-2.650
8. The pharmacy has a Class-M: Specialty (Bleeding Disorder) permit if the pharmacy is providing blood-clotting products to patients with bleeding disorders. [1]	YES NO N/A	20 CSR 2220-6.100
9. Storage sites used to store pharmaceuticals or confidential pharmacy records at a different address than the pharmacy are registered with the Board.	YES NO N/A	20 CSR 2220-2.010(1)(I)(J)
10. Any final adverse action taken against the pharmacy by another licensing state, jurisdiction or governmental agency was reported to the Board. See § 338.075 for add'l information. Action reports can be filed on the Board's website.	YES NO N/A	§ 383.075

[1] The pharmacy permit classes referenced represent the most common licensing violations noted on inspection. Other permit classifications exist that are not listed; See § 338.220 and 20 CSR 2220-2.020 for a complete list of all required pharmacy permit classes.

SUPPORT STAFF/PHARMACY SUPERVISION

STANDARD	RESPONSE	CITE
11. All pharmacist licenses, intern pharmacist licenses and technician registrations are current and posted or maintained in the pharmacy.	YES NO N/A	20 CSR 2220-2.010; § 338.013.4
12. All individual licenses, certificates, or registrations posted or maintained at the pharmacy have a 2"x2" photo displayed/attached.	YES NO N/A	20 CSR 2220-2.010(1)(E)
13. For technicians working on a pending technician application, a complete copy of the technician application submitted to the Board is kept in the pharmacy. To be complete, the application must be notarized, signed and include the correct fee and a fingerprinting receipt.	YES NO N/A	§ 338.013.3
14. All Board Licenses and registrants assisting in the practice of pharmacy are wearing an ID badge or similar article that includes their name and title (e.g., pharmacist, technician, intern)	YES NO N/A	20 CSR 2220-2.010(1)(L)
15. The Board regulatory sign indicating the pharmacy is licesned and regulated by the Board is prominently posted or electronically displayed in a publicly visible place.	YES NO N/A	20 CSR 2220-2.010(1)(L)3.
16. All technicians and intern pharmacists are supervised by a pharmacist.	YES NO N/A	20 CSR 2220-2.700(1)
17. For non-Class R Pharmacies: Technicians and intern pharmacists only compound or prepare prescriptions when a pharmacist is physically present.	YES NO N/A	20 CSR 2220-2.0100(1)(A)
18. For non-Class R pharmacies, technicians and intern pharmacists only sell or dispense prescriptions/medication to patients when a pharmacist is present (even if the Rx has been previously checked by a pharmacist).	YES NO N/A	20 CSR 2220-2.10(1)(A)
19. The "no pharmacist on duty" sign is posted when there is no pharmacist on duty.	YES NO N/A	20 CSR 2220-2.010(1)(A)
20. Pharmacy staffing is sufficient to safely provide patient care	YES NO N/A	§ 338.240(2)

STANDARD	RESPONSE	CITE
21. Technician disciplinary actions/resignations identified in § 338.013.10 were reported to the Board within 15 days. *Licensees are required to report disciplinary action/resignations for any conduct that may be cause to discipline under § 338.055. Action reports can be filed on the Board's website.	YES NO N/A	338.013(10); 20 CSR 2220-2.700(3)
22. Pharmacist disciplinary actions/resignations identified in § 383.133 were reported to the Board within 15 days. *Licensees are required to report disciplinary action/resignations for any conduct that may be cause to discipline under § 338.055. Action reports can be filed on the Board's website.	YES NO N/A	§ 383.133

PHARMACY CONDITIONS/MEDICATION STORAGE

STANDARD	RESPONSE	CITE
23. The pharmacy is maintained in a clean, orderly and sanitary manner.	YES NO N/A	20 CSR 2220-2.010(1)(G)
24. Trash/waste is appropriately disposed of.	YES NO N/A	20 CSR 2220-2.010(1)(G)
25. The pharmacy has a functioning hot & cold water supply and sewage disposal.	YES NO N/A	20 CSR 2220-2.010(1)(G)3.
26. Pharmacy equipment is clean and sanitary, including, the sink and any reconstitution device(s).	YES NO N/A	20 CSR 2220-2.010(1)(G)
27. Dispensing/compounding equipment is in good working condition.	YES NO N/A	20 CSR 2220-2.010(1)(G)
28. Medication in the pharmacy's inventory is stored separately from employee medications.	YES NO N/A	20 CSR 2220-2.010(2)(B)
29. Animals are not permitted in the pharmacy area, except as otherwise authorized by the Americans with Disabilities Act (ADA).	YES NO N/A	20 CSR 2220-2.010(1)(G)3.
30. The pharmacy regularly checks for outdated, distressed, misbranded, and adulterated drugs/devices.	YES NO N/A	20 CSR 2220-2.010(1)(G)3.

STANDARD	RESPONSE	CITE
31. All required reference materials are current and available in the pharmacy (manually or electronically).	YES NO N/A	20 CSR 2220-2.010(1)(D)
32. Pharmacy staff know how and where to access reference materials maintained electronically, including relief or "floating" staff.	YES NO N/A	20 CSR 2220-2.010(1)(D)
33. Medications are stored within the FDA approved or USP recommended temperatures and humidity requirements	YES NO N/A	20 CSR 2220-2.010(2)
34. All medication is stored in a thermostatically controlled area with a thermometer or temperature monitoring device/system	YES NO N/A	20 CSR 2220-2.010(2)(A)
35. Temperature control devices are working and properly functioning. Physically check temperature measurement device(s).	YES NO N/A	20 CSR 2220-2.010(2)(A)
36. Bulk compounding ingredients are stored in a clean, dry area and in properly labeled containers.	YES NO N/A	20 CSR 2220-2.400(6)(A)
37. Pharmacy staff wear disposable gloves when physically touching individual tablets/capsules, including, when bubble packing medication.	YES NO N/A	20 CSR 2220-2.010(1)(I)
38. Patient information is kept confidential and only disclosed as authorized by law.	YES NO N/A	§ 338.100
39. Stock bottles are not overfilled. (Check "yes" if this statement is correct). • This is misbranding!	YES NO N/A	§ 196.015
40. Physically check a sample of the pharmacy's inventory. Outdated, distressed, misbranded and adulterated drugs are quarantined and physically separated from the active inventory in a separate area that is clearly identified.	YES NO N/A	20 CSR 2220-2.010(2)(B)
41. Food and beverage items that are not in their original, sealed manufacturer packaging are stored separately from medication and medication-related devices.(Open food/beverages used in compounding or for patient use can be stored in same area if separated from other inventory and sanitary conditions are maintained)	YES NO N/A	20 CSR 2220-2.010(2)(C)

DRUG TAKE BACK

(Complete this section if the pharmacy is collecting medication for destruction under 20 CSR 2220-2.095. Skip this section if not applicable)

STANDARD	RESPONSE	CITE
42. Collection receptacles are securely placed inside the pharmacy's physical building.	YES NO N/A	20 CSR 2220-2.095
43. Collection receptacles are securely fastened to a permanent structure and are visible to pharmacy staff at all times.	YES NO N/A	20 CSR 2220-2.095
44. Collection receptacles are not located in or near exit doors.	YES NO N/A	20 CSR 2220-2.095
45. Collection receptacle inner liners are inventoried annually.	YES NO N/A	20 CSR 2220-2.095
46. Inner liners have a permanent, unique identification number/identifier that allows the liner to be tracked.	YES NO N/A	20 CSR 2220-2.095
47. Installation and removal of inner is supervised by two (2) Board licensees or registrants.	YES NO N/A	20 CSR 2220-2.095
48. Inner liners are immediately sealed once removed from the collection receptacle.	YES NO N/A	20 CSR 2220-2.095
49. Mail-back packages provided to the public for returning medication are pre-addressed with postage/shipping pre-paid.	YES NO N/A	20 CSR 2220-2.095(5)(A)
50. Mail-back packages are non-descript, and do not include any markings or other information that might indicate the package contains medication.	YES NO N/A	20 CSR 2220-2.095(5)(B)
51. Mail-back packages contain a unique identification number or other unique identifier to enable tracking.	YES NO N/A	20 CSR 2220-2.095(5)(E)
52. Mail-back packages are not returned to the pharmacy and are directly mailed by the public to a collector authorized to destroy medication under state/federal law.	YES NO N/A	20 CSR 2220-2.095(5)(A)
53. Collection receptacles and mail-back programs are not used to dispose of medication in the pharmacy's inventory	YES NO N/A	20 CSR 2220-2.095(3)
54. Medication destruction records are maintained for two (2) years.	YES NO N/A	20 CSR 2220-2.095(8)

CONTROLLED SUBSTANCES

STANDARD	RESPONSE	CITE
55. The pharmacy has DEA & BNDD registrations for each schedule of controlled substances possessed/dispensed and all registrations are current.	YES NO N/A	§ 195.030.2, RSMo; 21 CFR 1301.11
INVENTORY REQUIREMENTS		
56. An annual controlled substance inventory was taken for all controlled substances (including Schedule-V OTC pseudoephedrine products).	YES NO N/A	19 CSR 30-1.042
57. The annual inventory for Schedule-II controlled substances is documented separately from the annual inventory for Schedule III-V controlled substances.	YES NO N/A	19 CSR 30-1.042
58. The date & time the annual inventory was completed is documented on the inventory (e.g., beginning/close of business).	YES NO N/A	21 CFR 1304.11(a)
59. If the pharmacist-in-charge has changed, a controlled substance inventory was completed at or immediately prior to the PIC change.	YES NO N/A	20 CSR 2220-2.090(2)
SECURITY		
60. The pharmacy has adequate security to prevent unauthorized access to controlled substances and to deter theft.	YES NO N/A	19 CSR 30-1.031
61. Schedule-II controlled substances are stored in a locked/substantially constructed cabinet.	YES NO N/A	19 CSR 30-1.034
62. The Schedule-II controlled substance cabinet remains locked except when accessing drugs (cabinet keys should not be kept in the lock readily available to pharmacy staff).	YES NO N/A	19 CSR 30-1.034
63. Have all controlled substance losses been reported to DEA and BNDD within the required time frame and a copy of the reports maintained in the pharmacy?	YES NO N/A	21 CFR § 1301.76, 19 CSR 30-1.032(3)
DRUG PURCHASES/TRANSFER		
64. Medication is transferred either by invoice (schedule III-V) or via CSOS/a DEA 222 form (Schedule II).	YES NO N/A	§ 338.330, § 338.333/ 21 CFR 1305.3
65. All Schedule-III to Schedule-V invoices are dated when received.	YES NO N/A	19 CSR 30-1.048(4)

STANDARD	RESPONSE	CITE
66. Invoices for Schedule III-V controlled substances include the address and DEA number for both parties.	YES NO N/A	§ 338.330, § 338.333/ 21 CFR 1305.3
67. DEA Power of Attorney forms are current and have been completed for all pharmacy staff authorized to execute DEA-222 forms or CSOS orders.	YES NO N/A	21 CFR 1305.5
68. CSOS usernames/passwords are not shared or used by other people.	YES NO N/A	21 CFR 1305.21
69. **Review a sample set of DEA 222 forms or CSOS orders from each vendor.** All DEA 222 forms have been properly completed and all CSOS orders have been electronically checked into the CSOS system (including distributions to other pharmacies/ reverse distributors).	YES NO N/A	21 CFR § 1305.13, § 1305.22
70. Records of drugs transferred by invoice/DEA-222 are maintained for two (2) years.	YES NO N/A	21 CSR 1304.04
SCHEDULE V- OTC PSEUDOEPHEDRINE PRODUCTS		
71. If selling over-the-counter pseudoephedrine products, the pharmacy's DEA self-certification of compliance for the Combat Methamphetamine Act has been renewed annually.	YES NO N/A	21 USC § 830(e)(1)(B)
72. All OTC sales of pseudoephedrine products are reported to Missouri's approved database (NPLEx).	YES NO N/A	19 CSR 30-1.074
73. All NPLEx users have their own database password.	YES NO N/A	19 CSR 30-1.074(3)(M)
74. NPLEx passwords are not shared/used by other persons.	YES NO N/A	19 CSR 30-1.074(3)(M)

GENERAL DISPENSING

STANDARD	RESPONSE	CITE
75. Medication is only dispensed for humans pursuant to a patient-specific prescription or, for Class-B Hospital pharmacies, pursuant to a patient-specific medication order.	YES NO N/A	§ 338.095; § 338.165
76. Prescriptions for human use are not used to dispense medication to a prescriber for office stock or for office use. (Mark "yes" if this is correct).	YES NO N/A	§ 338.095
77. Child-resistant containers are used as required by the Federal Poison and Prevention Packaging Act.	YES NO N/A	16 CFR 1700.14
78. A prescription is required to flavor any over-the-counter medication.	YES NO N/A	20 CSR 2220-2.400(10)
79. Except as otherwise authorized by law, all prescriptions are verified by a licensed pharmacist prior to dispensing.	YES NO N/A	20 CSR 2220-2.010(1)(B)
80. A pharmacist verifies all compounded or reconstituted products/preparations.	YES NO N/A	20 CSR 2220-2.010(1)(B)
81. The name of the pharmacist responsible for reviewing data accuracy for each original prescription is documented in the pharmacy's prescription record system.	YES NO N/A	20 CSR 2220-2.017(1)(J)
82. If different from the pharmacist reviewing data accuracy, the identity of the pharmacist responsible for verifying the final product prior to dispensing is documented in the pharmacy's prescription record system (required for all prescriptions original and refill).	YES NO N/A	20 CSR 2220-2.017(1)(J)
83. Faxed prescriptions are only received from a prescriber's office or agent.	YES NO N/A	20 CSR 2220-2.085
84. Paper prescriptions with an electronic signature are applied to security paper that can detect/identify alterations or copying. *Security paper not required if manually signed, however, CMS may have additional requirements.	YES NO N/A	20 CSR 2220-2.085
85. Any changes/alterations made to the prescription are documented in the pharmacy's records.	YES NO N/A	20 CSR 2220-2.018(1)(H)
86. Drugs that have been rated inequivalent by the FDA are not substituted (B-rated).	YES NO N/A	§ 338.056

STANDARD	RESPONSE	CITE
87. The maximum expiration date on repackaged medication is twelve (12) months from the date of repackaging or the manufacturer's expiration date, whichever is earlier. This includes drugs in automated devices.	YES NO N/A	20 CSR 2220-2.130(1)(D)
88. Medication is transferred to other practitioners/entities either by invoice (non-controlled and schedule III-V) or via CSOS/a DEA 222 form (Schedule II).	YES NO N/A	§ 338.330, § 338.333/ 21 CFR 1305.3
89. For pharmacies using a vacuum tube delivery system, patients are positively identified before medication is dispensed via the vacuum tube system	YES NO N/A	20 CSR 2220-2.800(2)
90. Except as otherwise authorized by law, drug samples are not dispensed by or maintained in the pharmacy	YES NO N/A	20 CSR 2220-2.010(8)
91. Return-to-stock prescriptions are not poured back into the original stock container (This is misbranding/adulteration and violates state/federal law)	YES NO N/A	20 CSR 2220-3.040
92. Return to stock prescriptions are only returned to the automated filling system/unit that the medication was dispensed from, or the return to stock medication is maintained in the original patient container with the drug name, dispensing date and the prescription number/unique identifier visible on the container. ***Except as allowed for long-term care return/reuse, return to stock is only allowed if the medication was not dispensed to the patient and maintained in accordance with USP or manufacturer's recommendations.	YES NO N/A	20 CSR 2220-3.040(3)
93. For return-to-stock items, the dispensing has been deleted in the pharmacy's records and any third party payor claims have been reversed/credited	YES NO N/A	20 CSR 2220-3.040(3)
94. Policies/procedures are in place to ensure delivered medication is maintained/delivered within temperature requirements recommended by the manufacturer or the United States Pharmacopeia (USP)	YES NO N/A	20 CSR 2220-2.013(1)
PATIENT COUNSELING		
95. The pharmacy collects and maintains appropriate patient information to facilitate counseling (i.e.- clinical information, disease states, allergies)	YES NO N/A	20 CSR 2220-2.190(1)
96. For non-Class R pharmacies, patients are offered an opportunity to consult with a pharmacist each time a prescription is dispensed (new and refill).	YES NO N/A	20 CSR 2220-2.190
97. For Class R pharmacies, patient counseling is provided on all dispensed prescriptions , unless refused by the patient. *An offer to counsel is not sufficient.	YES NO N/A	20 CSR 2220-2.680(5)(B)

STANDARD	RESPONSE	CITE
98. Patient counseling is only provided by a licensed pharmacist or a licensed intern pharmacist under the pharmacist's supervision.	YES NO N/A	20 CSR 2220-2.190(1)
PRESCRIPTION TRANSFERS		
99. Prescription transfer requests received form a patient are completed within one (1) business day of the patient's request, unless otherwise prohibited by law.	YES NO N/A	20 CSR 2220-2.120(3)
100. Prescription transfer requests that are not received from the patient (e.g., another pharmacy) are transferred in a timely manner, and in a manner that ensures no interruption in patient therapy occurs.	YES NO N/A	20 CSR 2220-2.120(3)
101. Prescriptions transferred out of the pharmacy are voided in the pharmacy's records to prevent further dispensing. (See exemption in 20 CSR 2220-2.120(4) for Class-C Long Term Care pharmacies transferring prescriptions/orders for initial dispensing)	YES NO N/A	20 CSR 2220-2.120(2)
102. Controlled substance prescription transfers are only transferred between licensed pharmacists.	YES NO N/A	20 CSR 2220-2.120(1)
103. Review a sample of transfer records and answer the following: For prescriptions transferred out of the pharmacy, the pharmacy's records include: a. The transfer date b. The identity of the person transferring and receiving the transferred prescription/medication order c. For pharmacies using a manual prescription system, the word "void" appears on the prescription/medication order. For pharmacies using an electronic system, the prescription/medication order is voided in the system	YES NO N/A	20 CSR 2220-2.120(2)
CLASS-J SHARED SERVICES (For pharmacies engaged in shared services. See 20 CSR 2220-2.650 for definition of shared services)		
104. Both pharmacies participating in the shared services agreement have the same owner or have a written contract outlining the services to be provided by each party and their responsibilities	YES NO N/A	20 CSR 2220-2.650(1)(A)1.
105. Each location involved in providing shared services has a separate Class-J pharmacy permit.	YES NO N/A	20 CSR 2220-2.650(1)(A)
106. Each pharmacy participating in the shared services arrangement share a common database or have access to each pharmacy's prescription and patient records as needed to safely and properly perform each service activities.	YES NO N/A	20 CSR 2220-2.650(1)(A)3.

STANDARD	RESPONSE	CITE
107. Each participating pharmacy has a detailed written description of authorized shared services that includes the name, address and permit number of all pharmacies involved.	YES NO N/A	20 CSR 2220-2.650(1)(C)
108. The involved pharmacies have a current and accurate policy and procedure manual that includes: a. The duties of each pharmacy b. A mechanism for tracking the prescription of medication order during each step in the process c. Security provisions for protecting the confidentiality and integrity of patient information d. Delivery procedures to ensure compliance with 20 CSR 2220-2.013, and e. A designation of the pharmacy responsible for offering patient counseling.	YES NO N/A	20 CSR 2220-2.650(1)(C)
109. The pharmacy maintains a quality assurance (QA) program to objectively monitor and evaluate the quality of pharmacy services and resolve problems	YES NO N/A	20 CSR 2220-2.650(1)(D)
110. If the pharmacy is participating in Class-J Shared Services with a pharmacy that is not under common ownership, the pharmacy notifies patients that their prescriptions/medication orders may be filled or compounded by another pharmacy. *The Bd recommends identifying approved notification methods in the pharmacy's policies and procedures.	YES NO N/A	20 CSR 2220-2.650(3)
111. Compounding is only performed pursuant to a patient-specific prescription or in anticipation of a patient-specific prescription as authorized by 20 CSR 2220-2.200	YES NO N/A	20 CSR 2220-2.650(3)

STANDARD	RESPONSE	CITE
112. The pharmacy maintains a quality assurance (QA) program to objectively monitor and evaluate the quality of pharmacy services and resolve problems	YES NO N/A	20 CSR 2220-2.650(1)(D)
113. If the pharmacy is participating in Class-J Shared Services with a pharmacy that is not under common ownership, the pharmacy notifies patients that their prescriptions/medication orders may be filled or compounded by another pharmacy. *The Bd recommends identifying approved notification methods in the pharmacy's policies and procedures.	YES NO N/A	20 CSR 2220-2.650(3)
114. Compounding is only performed pursuant to a patient-specific prescription or in anticipation of a patient-specific prescription as authorized by 20 CSR 2220-2.200	YES NO N/A	20 CSR 2220-2.650(3)
NICOTINE REPLACEMENT THERAPY (This section applies if pharmacists are prescribing nicotine replacement therapy (NRT) products, as authorized/defined by § 338.665, RSMo.		
115. Patient/medical history is collected prior to prescribing a nicotine replacement therapy product, as defined by § 338.665, RSMo.	YES NO N/A	20 CSR 2220-6.200(3)(A)
116. Screening procedures are used based on generally accepted clinic guidelines to identify appropriate patients for treatment.	YES NO N/A	20 CSR 2220-6.200(3)(A)
Review a sample of NRT patient records and answer the following: 117. Medical records are maintained for patients prescribed a nicotine replacement therapy product that include: a. The patient's name, birthdate, address and telephone number b. The date(s) the patient was seen c. The patient's primary care provider (if provided) d. Documentation of the required patient screening e. Any pertinent medical or medication information/history f. The name and dosage of any medication prescribed, g. Any recommended medication treatment plan(s) or follow-up consultation(s); and h. Any healthcare provider referrals.	YES NO N/A	20 CSR 2220-6.200(4)(A)

PRESCRIPTION REVIEW

STOP: *Licensees should manually review a sufficient sample of prescription records to verify compliance with the following requirements. Appropriate sample size will vary depending on pharmacy volume. At a minimum, the Board recommends reviewing 10% of the pharmacy's average weekly prescription volume.*		
118. All prescriptions have been assigned a consecutive number or a unique readily retrievable identifier.	YES NO N/A	§ 338.059
119. All reviewed prescriptions contain: a. The prescribing date b. The name of the patient(s) or, for animals, the species and owner's name. c. The prescriber's name (verbal prescriptions) or a written or electronic signature (written, faxed or electronic prescriptions) d. Name, strength and dosage of the medication, device or poison e. Directions for use f. Number of refills, if applicable g. Quantity (in weight, volume or # of units)	YES NO N/A	20 CSR 2220-2.018(1)
120. The correct drug, strength and quantity was dispensed on each prescription with the correct instructions for use.	YES NO N/A	20 CSR 2220-2.010
121. Except in cases of emergency dispensing, no more than the allowed and prescribed number of refills were dispensed.	YES NO N/A	20 CSR 2220-2.010
122. All reviewed prescription labels contain: f. The date the prescription was filled g. A prescription number or other unique identifier h. The prescriber's name i. The correct directions for use j. The pharmacy's name and address k. The exact name and dose of medication dispensed	YES NO N/A	§ 338.059

STANDARD	RESPONSE	CITE
CONTROLLED SUBSTANCES: In addition to the above requirements, the Board recommends reviewing a minimum of 25 controlled substance prescriptions in each schedule to verify compliance with the following:		
123. All reviewed controlled substance prescriptions also include: a. The prescriber's address b. The patient's address c. The prescriber's DEA number d. Dosage form	YES NO N/A	20 CSR 2220-2.018(1)
124. Controlled substance prescriptions issued by an advanced practice registered nurse (APRN) or assistant physician (AP) for Missouri patients include the name, telephone # and address of both the APRN/AP and the collaborating physician. **Effective August 28, 2023, physician assistant (PA) prescriptions do not have to include the collaborating physician's name.*	YES NO N/A	§ 334.735.4, 20 CSR 2200-4.200(3)(G).7.
125. All controlled substance prescriptions are manually signed by the prescriber except for DEA compliant electronic prescriptions.	YES NO N/A	21 CFR § 1306.8
126. All faxed controlled substance prescriptions are manually signed (stamped/electronic signatures are not allowed)	YES NO N/A	21 CFR 1306.05
127. No Schedule-II prescriptions were refilled. (Mark "yes" if this answer is correct)	YES NO N/A	21 CFR 1306.12(a)
128. If more than a 30-day supply of a Schedule-II controlled substance was dispensed, the specific medical reason for dispensing is documented on the prescription or on a form attached to the prescription. (Per BNDD, diagnosis alone is not a sufficient medical reason).	YES NO N/A	§ 195.080.2
130. Controlled substance partial fills comply with DEA and BNDD requirements.	YES NO N/A	19 CSR 30-1.064; 21 USC § 1306.13

NON-STERILE COMPOUNDING

STANDARD	RESPONSE	CITE
131. The pharmacy has a Class-D pharmacy permit if the pharmacy performs non-sterile compounding in batch quantities using bulk active ingredients.	YES NO N/A	20 CSR 2220-2.010(9)(D)
132. The pharmacy has compounding policies and procedures.	YES NO N/A	20 CSR 2220-2.400(7)(A)
133. The pharmacy has established quality control policies and procedures to ensure products have the proper identity, strength, quality and purity.	YES NO N/A	20 CSR 2220-2.400(7)(A)
134. The pharmacy maintains a drug monitoring system to evaluate the quality of compounding services.	YES NO N/A	20 CSR 2220-2.400(8)(B)
135. The required drug monitoring system evaluates/tracks reported infection rates, adverse drug reactions, recalls and prescriber/client complaints.	YES NO N/A	20 CSR 2220-2.400(8)(B)
136. A recall is initiated when a compounded product is deemed to be misbranded or adulterated.	YES NO N/A	20 CSR 2220-2.400(8)(C)
137. The Board is notified in writing within three (3) days of any recall related to a misbranded/adulterated compounded product.	YES NO N/A	20 CSR 2220-2.400(8)(C)
138. In the event of a recall of a misbranded/adulterated non-sterile compounded product, the prescriber is notified of the nature of the recall, the problems identified and any recommended actions to ensure public health or safety.	YES NO N/A	20 CSR 2220-2.400(8)(C)
139. The pharmacy does not compound commercially available products or products that are essential copies of commercially available products. Mark “yes” if this answer is correct. If “no” is marked, see question #140.	YES NO N/A	20 CSR 2220-2.400(9)
140. If a commercially available product is compounded, the pharmacy has documented that the commercially available product is unavailable or documented the specific medical need for compounding the product in the pharmacy’s records.	YES NO N/A	20 CSR 2220-2.400(9)
141. The pharmacy doesn’t make specific claims about compounded products without supporting analytical data (i.e., designating a product as sustained release, poison ivy prevention/relief or “bio-identical hormone replacement”). Mark “yes” if this answer is correct.	YES NO N/A	20 CSR 2220-2.400(12)

STANDARD	RESPONSE	CITE
SANITATION/DISPENSING		
142. Compounding areas are clean, sanitary and trash is properly disposed of.	YES NO N/A	20 CSR 2220-2.400(5)(A)
143. Equipment surfaces are not reactive, additive or absorptive in a manner that will alter the safety, identity, strength or quality of a compound.	YES NO N/A	20 CSR 2220-2.400(6)(E)
144. No expired ingredients or batch compounded products are in the compounding area. (Mark "yes" if this answer is correct).	YES NO N/A	20 CSR 2220-2.010(2)
145. All compounded prescriptions returned to stock have an in-house lot number and a beyond-use date designated on the container label and in the compound log. These are considered batched.	YES NO N/A	20 CSR 20 CSR 2220-2.400(7)(A), (D)
146. All bulk active ingredients meet compendial standards (USP, NF, etc) or a certificate of analysis for the bulk substance is on file (i.e.- camphor blocks).	YES NO N/A	20 CSR 2220-2.400(8)(A)2
147. Compounding records are maintained for 2-years from the compounding date.	YES NO N/A	20 CSR 2220-2.400(5)(A)
148. The actual name (no abbreviations) of each active or therapeutic ingredient is listed on the prescription container. • General designations are non-compliant (i.e.- "antacid").	YES NO N/A	20 CSR 2220-2.400(7)(F)
STOP: *Review the pharmacy's compounding log for the previous 3-6 months and assess the following:*		
149. The compounding log includes: a. The compounding method** b. Compounding date c. Identity of the compounding pharmacist d. A list of all drug products/ingredients and their amounts by weight or volume e. The source, lot number and beyond-use date for each drug product/ingredient f. In-house lot number and beyond-use date for bulk compounded products g. The prescription number/unique identifier, and h. A description of the compounding process and the order of drug products/ingredient addition, if necessary for proper compounding.** ** This information may be separately stored in the pharmacy's records if immediately retrievable.	YES NO N/A	20 CSR 2220-2.400(7)(A)

STANDARD	RESPONSE	CITE
150. No expired drugs were used in compounding. Mark "yes" if this statement is correct.	YES NO N/A	20 CSR 2220-2.010(2)

STERILE COMPOUNDING (ALL RISK LEVELS):

The Board anticipates issuing a separate self-assessment form for sterile compounding in the future. In the interim, licensees should review 20 CSR 2220-2.200 and the Practice Guide to ensure compliance with Missouri law.

IMMUNIZATIONS under 338.010.1(4)

STANDARD	RESPONSE	CITE
151. Immunizing pharmacists have filed a Notification of Intent to immunize with the Board.	YES NO N/A	20 CSR 2220-6.050(3)
152. Immunizations are only administered to patients 7-years of age or older.	YES NO N/A	§ 338.010.1
153. The pharmacy does not administer any vaccine approved after January 1, 2023, or: cholera, monkeypox, Japanese encephalitis, typhoid, rabies, yellow fever, tick-borne encephalitis, anthrax, tuberculosis, dengue, Hib, polio, rotavirus, or smallpox	YES NO N/A	§ 338.010.1
154. Immunizations are only delegated to an intern pharmacist or a "qualified pharmacy technician" who meets the requirements of 20 CSR 2220-6.050(1)(E)	YES NO N/A	20 CSR 2220-6.050(1)(E)
155. All immunizing pharmacists, intern pharmacists and qualified pharmacy technicians hold a current CPR or basic life support (BLS) certification as required by 20 CSR 2220-6.050(3)(B)	YES NO N/A	20 CSR 2220-6.050(3)(B)
156. All immunizing pharmacists, intern pharmacists and qualified pharmacy technicians have completed a certificate program in administering vaccines, as required by 20 CSR 2220-6.050(3)(C)	YES NO N/A	20 CSR 2220-6.050(3)(C)
157. All qualified pharmacy technicians administering vaccines: a. Hold an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies (currently PTCB and ExCPT/NHA are accredited), and b. Has an initial and annual documented competency assessment, and c. Has assisted in the practice of pharmacy as a registered technician in Missouri or another U.S. state/territory, for at least one (1) year.	YES NO N/A	20 CSR 2220-6.050(1)(E)
158. Patients are asked to remain in the pharmacy for a "safe amount of time" after being immunized to observe any adverse reactions.	YES NO N/A	§ 338.010.12
159. A Missouri-licensed pharmacist is physically present on-site whenever a qualified pharmacy technician is administering vaccines.	YES NO N/A	20 CSR 2220-6.050(8)

STANDARD	RESPONSE	CITE
Review the current immunization protocol for compliance with the following: **This section only applies to pharmacists opting to immunize by protocol. Effective August 8, 2023, a physician protocol is optional but not required.		
160. All immunizing pharmacists have signed and dated the immunization protocol and the protocol is not expired.	YES NO N/A	20 CSR 2220-6.050(4)
161. All immunization protocols contain: a. The name and signature of all participating pharmacist(s) and physician(s) b. The time period of the protocol c. Authorized vaccines d. A list of the patient/patient groups the pharmacist is authorized to immunize e. The authorized routes and anatomic sites of administration f. Emergency response procedures, including, adverse reactions, anaphylactic reactions and accidental needle sticks g. The length of time pharmacists are required to observe a patient for adverse reactions after an injection h. Provisions for disposing of used/contaminated supplies i. If applicable, authorization to administer vaccines at a non-pharmacy location. *This item not required if the pharmacist is not authorized to administer outside of a pharmacy. Street addresses of non-pharmacy locations no longer have to be listed in the protocol. j. Procedures for record-keeping and immunization notifications k. Provisions for terminating the protocol l. Patient assessment or referral requirements, if applicable	YES NO N/A	20 CSR 2220-6.050(4)
STOP: *Review a representative sample of the pharmacy's immunization records to evaluate compliance with the following:*		
162. Immunization records are maintained for at least two (2) years.	YES NO N/A	20 CSR 2220-6.050(5)(C).4
163. Immunization records are stored separately from the pharmacy's prescription files.	YES NO N/A	20 CSR 2220-6.050(5)(C)

STANDARD	RESPONSE	CITE
164. Immunization records include: a. The patient's name, address and DOB b. The date and route of administration c. The anatomic site of administration (this is a common violation) d. The vaccine's name, dose, manufacturer, lot number and expiration date e. The name and address of the patient's PCP (if provided) f. The identity of the administering pharmacist or the administering intern and the intern's supervising pharmacist	YES NO N/A	20 CSR 2220-6.050(5)(A)
165. For immunizations administered by protocol, a prescription was created under the protocol physician's name within 72-hours of immunization or a prescription was obtained from the authorizing physician within the required 72-hours.	YES NO N/A	20 CSR 2220-6.050(5)(B)
166. For immunizations ordered or administered by a pharmacist, a prescription was created in the pharmacist's name within seventy-two (72) hours.	YES NO N/A	20 CSR 2220-6.050(5)(B)
167. All notifications required by protocol were timely made (if applicable). Notifications are required as specified in the protocol; The Board's rules no longer include a mandatory notification time except for adverse events.	YES NO N/A	20 CSR 2220-6.050(6)(A)
168. The patient's PCP and, if immunizing by protocol, the protocol physician were notified of an adverse event/reaction within twenty-four (24) hours. *Notification to the PCP is required if known for adverse events.	YES NO N/A	20 CSR 2220-6.050(6)(D)
169. Adverse events/reactions were reported to the Vaccine Adverse Event Reporting System (VAERS) within thirty (30) days.	YES NO N/A	20 CSR 2220-6.050(6)(D)
170. The dates of required notifications are documented in the pharmacy's records.	YES NO N/A	20 CSR 2220-6.050(6)(E)
171. Immunizations are reported to ShowMeVax or the patient's PCP as required by statute. Note: Additional federal reporting requirements may apply (e.g. COVID-19 vaccines)	YES NO N/A	§ 338.010.13

MEDICATION ADMINISTRATION BY MEDICAL PRESCRIPTION ORDER

STANDARD	RESPONSE	CITE
STOP: *Review a sample of the pharmacy's administration records to evaluate compliance with the following:*		
172. All administering pharmacists have filed a Notification of Intent to administer by prescription order with the Board. (This is different from a Notification of Intent to immunize by protocol).	YES NO N/A	20 CSR 2220-6.040(3)
173. All administration prescription orders contain the: a. Date of the original order b. Prescriber's name c. Patient's name d. Name of drug and dose to be administered e. Route of administration f. If applicable, the date or schedule of any subsequent administrations	YES NO N/A	20 CSR 2220-6.040(5)
174. Administration of medication is only delegated to an intern pharmacist or a "qualified pharmacy technician" who meets the requirements of 20 CSR 2220-6.040(2) & (3)	YES NO N/A	20 CSR 2220-6.040(2), (3)
175. Pharmacists, intern pharmacists and qualified pharmacy technicians administering medication hold a current CPR or basic life support (BLS) certification as required by 20 CSR 2220-6.040(3)(B)	YES NO N/A	20 CSR 2220-6.040(3)(B)
176. Pharmacists, intern pharmacists and qualified pharmacy technicians administering medication have completed a certificate program in medication administration as required by 20 CSR 2220-6.040(3)(C)	YES NO N/A	20 CSR 2220-6.040(3)(C)
177. All qualified pharmacy technicians administering medication: a. Hold an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies (currently PTCB and ExCPT/NHA are accredited), and b. Has an initial and annual documented competency assessment, and c. Has assisted in the practice of pharmacy as a registered technician in Missouri or another U.S. state/territory, for at least one (1) year.	YES NO N/A	20 CSR 2220-6.040(2)(A)

STANDARD	RESPONSE	CITE
178. A Missouri-licensed pharmacist is physically present on-site whenever a qualified pharmacy technician is administering medication.	YES NO N/A	20 CSR 2220-6.040(9)
179. Vaccines are reported to ShowMeVax or the patient's PCP as required by statute/rule.	YES NO N/A	§ 338.010.13; 20 CSR 2220-6.040(7)(A)
180. The prescriber was notified of any adverse events/reactions within twenty-four (24) hours.	YES NO N/A	20 CSR 2220-6.040(7)(B)
181. Any other notification required by state/federal law was made.	YES NO N/A	20 CSR 2220-6.040(7)(C)
182. For vaccines, adverse events/reactions were reported to the Vaccine Adverse Event Reporting System (VAERS) within thirty (30) days.	YES NO N/A	20 CSR 2220-6.040(7)(B)

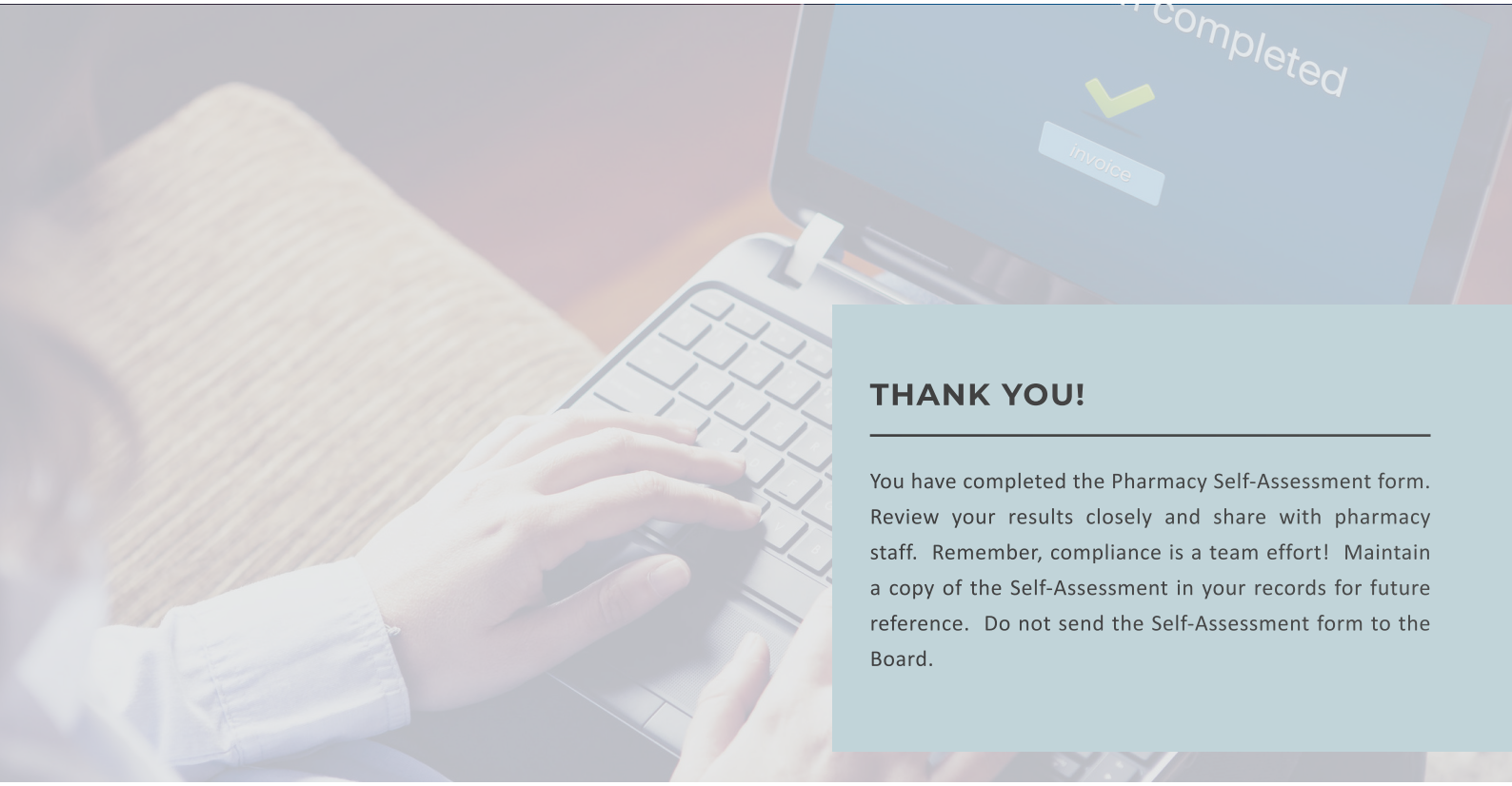
POLICIES AND PROCEDURES

STANDARD	RESPONSE	CITE
183. The pharmacy has written policy and procedures for the following pharmacy services/activities (if applicable):		
a. Automated Dispensing and Storage Systems	YES NO N/A	20 CSR 2220-2.900(1)(B)
b. Administration by Medical Prescription Order	YES NO N/A	20 CSR 2220-6.040(4)
c. Automated Filling Systems	YES NO N/A	20 CSR 2220-2.950(4)
d. Class-C Long-Term Care	YES NO N/A	20 CSR 2220-2.140(2)
e. Class-F Renal Dialysis Services	YES NO N/A	20 CSR 2220-2.600(2)(E)
f. Class-H Sterile Product Compounding	YES NO N/A	20 CSR 2220-2.200(2)
g. Class-J Shared services	YES NO N/A	20 CSR 2220-2.650(1)(C)
h. Class-L Veterinary Pharmacies	YES NO N/A	20 CSR 2220-2.675(5)(C)
i. Class-M Specialty (Bleeding Disorder)	YES NO N/A	20 CSR 2220-6.100(4)
j. Class N & O (Automated Dispensing System)	YES NO N/A	20 CSR 2220-2.900
k. Class R Remote Dispensing Site	YES NO N/A	20 CSR 2220-2.680(5)(C); § 338.215.2(3)

STANDARD	RESPONSE	CITE
l. Drug Take Back	YES NO N/A	20 CSR 2220-2.095(3)
m. Electronic Record-Keeping System	YES NO N/A	20 CSR 2220-2.083(4)
n. Prescription delivery (including mail order)	YES NO N/A	20 CSR 2220-2.013(1)
o. Remote Data Entry Sites	YES NO N/A	20 CSR 2220-2.725(4)

REMOTE DATA ENTRY SITES

STANDARD	RESPONSE	CITE
184. The pharmacy has an address listing of all remote data entry sites that is current	YES NO N/A	20 CSR 2220-2.725(2)(A)
185. All remote data entry sites are located in Missouri or another U.S. state or territory.	YES NO N/A	20 CSR 2220-2.725(1)(A)
186. All remote data entry sites and the supervising pharmacy share a common database or prescription record-keeping system that allows both the supervising pharmacy and the remote data entry site(s) real-team online access to relevant patient profile information	YES NO N/A	20 CSR 2220-2.725(2)(B)
187. The pharmacy has written policies/procedures governing all aspects of remote data entry site operations, including: a. Authorized technician and intern pharmacist activities b. Remote data entry site security c. Security breach reporting d. Quality assurance review e. Staff education/training	YES NO N/A	20 CSR 2220-2.725(4)
188. All intern pharmacists and pharmacy technicians at a remote data entry site have completed employer approved training in the activities being performed remotely	YES NO N/A	20 CSR 2220-2.725(3)(C)
189. All intern pharmacists and pharmacy technicians at a remote data entry site have an initial and annual documented competency assessment.	YES NO N/A	20 CSR 2220-2.725(3)(C)



THANK YOU!

You have completed the Pharmacy Self-Assessment form. Review your results closely and share with pharmacy staff. Remember, compliance is a team effort! Maintain a copy of the Self-Assessment in your records for future reference. Do not send the Self-Assessment form to the Board.

ASSESSMENT COMPLETED BY:

DATE:

MISSOURI BOARD OF PHARMACY
SELF-ASSESSMENT CONTINUING EDUCATION
CERTIFICATION FORM

The Board has approved two (2) hours of continuing education credit for pharmacy managers, owners, supervisors or pharmacist-in-charge for each calendar year the licensee completes the Self-Assessment. To be eligible for CE, this Certification Form must be returned to the Board before December 31st of the applicable calendar year. Self-Assessments completed after the biennial continuing education deadline will not be eligible for credit for the preceding renewal period.

NAME OF LICENSEE COMPLETING SELF ASSESSMENT	MO PHARMACIST LICENSE #	Position/Title	Date

LICENSEE ADDRESS (ADDRESS OF PERSON REQUESTING CE)	CITY, STATE	ZIP

PHARMACY ADDRESS (ADDRESS OF PHARMACY REVIEWED)	CITY, STATE	ZIP

PHARMACY PERMIT NUMBER	DATE SELF-ASSESSMENT COMPLETED

I, the undersigned person, do hereby attest that I have completed the Self-Assessment for the pharmacy identified above and request continuing education (CE) credit.

_____ _____

Licensee Signature **Print Name**

*****Your CE certificate will be mailed to the licensee address listed above*****

Mail this certification to:
Missouri Board of Pharmacy
Attn: Compliance Coordinator
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, Missouri 65109